

REMARKS

This responds to the Office Action dated April 18, 2006 (hereinafter “Office Action”), and the references cited therewith.

Claims 1, 11, 18, 20, 24, and 28 are amended, claims 8, 14, 19, 21, 22, and 27 are canceled, and no claims are added; as a result, claims 1-7, 9-13, 15-18, 20, 23-26, and 28-31 are now pending in this application. Applicant submits that the amendments to the claims are fully supported by the specification as originally filed, and no new matter has been added.

Applicant hereby respectfully requests further examination and reconsideration of the application in view of the foregoing claims amendments and following remarks.

§102 Rejection of the Claims

Claims 1-7, 9-13, 15-20, 22, 24-26 and 29 were rejected under 35 U.S.C. § 102(b) as being anticipated by Cobain et al. (U.S. Patent No. 5,796,044).

Anticipation requires that the claimed subject matter be “identically disclosed” in the prior art. *In re Arkley*, 172 U.S.P.Q. 524, 526 (C.C.P.A. 1972). The reference relied upon must teach or suggest all the limitations of the claims. *See In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970)(stating “[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art”)(emphasis added).

Claims 1-7 and 9-10:

Applicant submits that the cited reference, Cobain, fails to anticipate claims 1-7 and 9-10 because, among other things, Applicant cannot find “identically disclosed” claimed elements and/or limitations in such reference, as required by *In re Arkley*.

Claim 1:

Among other things, Applicant’s claim 1 recites “[a] lead assembly . . . wherein the first conductor and the second conductor are rotatable relative to one another.” As recognized by the Office Action, “Cobain et al. disclose[s] the claimed invention except for a means for facilitating rotation of the second conductor relative to the first conductor.” (Office Action, page 3).

Because not all elements and/or limitations of Applicant's claim 1 can be found in Cobain, Applicant respectfully requests withdrawal of this basis of rejection of claim 1. Claims 2-7 and 9-10 are dependent on claim 1 and are patentable over Cobain for the reasons stated above, in addition to the elements and/or limitations in such claims.

Claim 4 and 5:

In addition to the foregoing reasons supporting a finding of patentability of claims 1-7 and 9-10 (of which claims 4 and 5 are included), Applicant submits that Cobain fails to identically disclose a lead assembly "wherein the insulative sleeve comprises a tube of polyurethane, polyimide, or polysiloxane urethane disposed between the first conductor and the second conductor," as recited in claim 4, and further fails to identically disclose a lead assembly "wherein the insulative sleeve is comprised of a non-silicone material," as recited in claim 5.

As to claim 4, the Office Action asserts that such subject matter may be found at "fig. 9; col. 4 @ 11-15; col. 11 @ 4-6." (Office Action, page 2). Applicant submits that while FIG. 9 and col. 11 @ 4-6 illustrates/recites a "separating sheath 38 is provided intermediate the inner insulative sheath 27 and the outer insulative sheath 22," nowhere does Cobain recite an insulative sleeve "compris[ing] a tube of polyurethane, polyimide, or polysiloxane urethane," as recited in claim 4. Applicant further submits that, as recognized by the Office Action, col. 4 @ 11-15 pertains to "an insulative coating disposed directly [on an outer filar surface of a first or second conductor] such that a cross-section of the outer filar surface is surrounded by the insulative coating," and not to an "insulative sleeve disposed between the first conductor and the second conductor," as to which claim 4 pertains. (Office Action, page 2; *see also* Cobain, col. 4, lines 7-15).

As to claim 5, the Office Action asserts that such subject matter may be found at "col. 5 @ 57-67; col. 12 @ 42-50." (Office Action, page 2). Applicant submits that such cited portions of Cobain pertain to "coiled insulative sheaths 42, 82, 84," which, as shown in FIGS. 10 and 12, are the sheaths disposed around the outer filar surface of the first and second conductors, and not to the insulative sleeve (e.g., 38) therebetween, as recited in claim 5. That is, the cited portions of Cobain fail to recite "wherein the insulative sleeve is comprised of a non-silicone material," as recited in claim 5.

Because not all elements and/or limitations of Applicant's claims 4 and 5 can be found in Cobain, Applicant respectfully requests withdrawal of this basis of rejection of claims 4 and 5.

Claims 11-13, 15-17, and 30-31:

Applicant submits that the cited reference, Cobain, fails to anticipate claims 11-13, 15-17, and 30-31 because, among other things, Applicant cannot find "identically disclosed" claimed elements and/or limitations in such reference, as required by *In re Arkley*.

Claim 11:

Among other things, Applicant's claim 11 recites "[a] lead assembly comprising . . . a tubular insulative sleeve disposed between the first conductor and the second conductor, the tubular insulative sleeve comprising one or both of polyurethane or polyimide; and the second conductor disposed within and rotatable relative to the first conductor." As recognized by the Office Action, "Cobain et al. disclose[s] the claimed invention except for the insulation/coating being a polyimide material." (Office Action, page 4). As further recognized by the Office Action, "Cobain et al. disclose[s] the claimed invention except for a means for facilitating rotation of the second conductor relative to the first conductor." (Office Action, page 3). Moreover, as discussed above in association with claim 5, the cited portions of Cobain fail to recite an insulative sleeve comprising a non-silicone material, such as polyurethane, as further recited in claim 11.

Because not all elements and/or limitations of Applicant's claim 11 can be found in Cobain, Applicant respectfully requests withdrawal of this basis of rejection of claim 11. Claims 12-13, 15-17, and 30-31 are dependent on claim 11 and are patentable over Cobain for the reasons stated above, in addition to the elements and/or limitations in such claims.

Claim 30:

In addition to the foregoing reasons supporting a finding of patentability of claims 11-13, 15-17, and 30-31, Applicant submits that Cobain fails to identically disclose a lead assembly "wherein the tubular insulative sleeve is rotatable relative to the first conductor," as recited in claim 30. The Office Action asserts that such subject matter may be found at "col. 4 @ 7-15;

col. 5 @ 12-60; col. 11 @ 4-6.” (Office Action, page 3). Applicant submits that while col. 11 @ 4-6 recites a “separating sheath 38 is provided intermediate the inner insulative sleeve,” nowhere does Cobain recite that the “insulative sleeve is rotatable relative to the first conductor,” as recited in claim 30. The Office Action cited portions “col. 4 @ 7-15; col. 5 @ 12-60” pertain to “an insulative coating disposed directly [on an outer filar surface of a first or second conductor] such that a cross-section of the outer filar surface is surrounded by the insulative coating,” and not to an “insulative sleeve disposed between the first conductor and the second conductor,” as to which claim 30 pertains. (Office Action, page 2; *see also, e.g.*, Cobain, col. 4, lines 7-15).

Because not all elements and/or limitations of Applicant’s claim 30 can be found in Cobain, Applicant respectfully requests withdrawal of this basis of rejection of claim 30.

Claims 18, 20, and 23:

Applicant submits that the cited reference, Cobain, fails to anticipate claims 18, 20, and 23 because, among other things, Applicant cannot find “identically disclosed” claimed elements and/or limitations in such reference, as required by *In re Arkley*.

Among other things, Applicant’s claim 18 recites “[a] method comprising . . . disposing one or both of polyurethane or polyimide tubing between the first conductor and the second conductor.” As recognized by the Office Action, “Cobain et al. disclose[s] the claimed invention except for the insulation/coating being a polyimide material.” (Office Action, page 4). In addition, as discussed above in association with claim 5, the cited portions of Cobain fail to recite an insulative sleeve comprising a non-silicone material, such as polyurethane, as further recited in claim 18.

Because not all elements and/or limitations of Applicant’s claim 18 can be found in Cobain, Applicant respectfully requests withdrawal of this basis of rejection of claim 18. Claims 20 and 23 are dependent on claim 18 and are patentable over Cobain for the reasons stated above, in addition to the elements and/or limitations in such claims.

Claims 24-26 and 28-29:

Applicant submits that the cited reference, Cobain, fails to anticipate claims 24-26 and 28-29 because, among other things, Applicant cannot find “identically disclosed” claimed elements and/or limitations in such reference, as required by *In re Arkley*.

Among other things, Applicant’s claim 24 recites “[a] method comprising . . . heat shrinking PTFE or ETFE on the second outer coil diameter and over the insulation.” As recognized by the Office Action, “Cobain et al. . . . do[es] not teach applying heat shrunken . . . material on the second outer coil diameter and insulation.” (Office Action, page 4).

Because not all elements and/or limitations of Applicant’s claim 24 can be found in Cobain, Applicant respectfully requests withdrawal of this basis of rejection of claim 24. Claims 25-26, and 28-29 are dependent on claim 24 and are patentable over Cobain for the reasons stated above, in addition to the elements and/or limitations in such claims.

§103 Rejection of the Claims

Claims 8 and 14 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Cobain et al. (U.S. Patent No. 5,796,044) in view of Helland et al. (U.S. Patent No. 5,545,201). Claims 21, 23 and 30 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Cobain et al. in view of Altman et al. (U.S. Patent No. 5,845,396). Claims 23, 27 and 28 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Cobain et al. in view of Nelson et al. (U.S. Patent No. 6,249,708). Applicant respectfully traverses these rejections and submits that the Office Action has not made out a *prima facie* case of obviousness.

To establish a *prima facie* case of obviousness, three criteria must be met.

First, there must be some suggestion or motivation, either in the cited reference(s), or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. MPEP § 2142 (citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d (BNA) 1438 (Fed. Cir. 1991)). According to *In re Lee*, “there must be some motivation, suggestion, or teaching of the desirability of making the specific combination that was made by the applicant.” 61 USPQ2d 1430 (Fed. Cir. 2002)(citing *In re Fine*), *see also ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984)(holding “[o]bviousness cannot be established by combining the teachings of the prior art

to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination”).

As further stated by *In re Lee*, the “factual question of motivation is material to patentability, and [*can*] not be resolved on subjective belief and unknown authority.” *In re Lee* (emphasis added). “We do not ‘pick and choose among the individual elements of assorted prior art references to recreate the claimed invention,’ but rather, we look for ‘some teaching or suggestion in the references to support their use in the particular claimed combination.’” *Symbol Technologies, Inc. v. Opticon, Inc.*, 935 F.2d 1569, 19 U.S.P.Q.2d 1241 (Fed. Cir. 1991). Motivation to combine requires desirability, not merely a trade-off. Trade-offs often concern what is feasible, not what is necessarily desirable. Motivation to combine requires the latter. *Winner International Royalty Corp. v. Wang*, 202 F.3d 1340, 53 U.S.P.Q.2d 15080 (Fed. Cir.), *cert. denied*, 530 U.S. 1238 (2000).

A factor cutting against a finding of motivation to combine or modify the prior art is when the prior art teaches away from the claimed combination. A reference should be considered as a whole, and portions arguing against or teaching away from the claimed invention must be considered. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 230 USPQ 416 (Fed. Cir. 1986).

The examiner must provide a *specific reason* to support an obviousness rejection. *Ex parte Humphreys*, 24 USPQ2d 1255 (BPAI 1992). An examiner’s assertion that a modification proposed is “an obvious matter of design choice” is an unsupported conclusion – not a reason upon which to base a rejection. *See In re Garrett*, 33 BNA PTCJ 42 (November 13, 1986); *see also In re Gal*, 980 F.2d 717, 25 USPQ2d 1076 (Fed. Cir. 1992)(rejecting an “obvious design choice” rejection wherein the claimed structure and its function are different from the prior art).

Second, the prior art reference(s) must teach or suggest all of the claim elements and/or limitations. MPEP § 2142.

Third, there must be a reasonable expectation of success. MPEP § 2142.

Claims 8 and 14:

The subject matter of claims 8 and 14 has been incorporated into respective independent claims 1 and 11; claims 8 and 14 have been canceled. Applicant submits that the Office Action

has failed to make out a *prima facie* case of obviousness for (now canceled) claims 8 and 14, and thus claims 1 and 11, because not all claim elements and/or can be found in Cobian nor Helland (either individually or in combination), as required by M.P.E.P. § 2142.

In addition to the foregoing grounds set forth supporting the patentability of Applicant's claims 1-7 and 9-10 and claims 11-13, 15-17, and 30-31, Applicant cannot find in the cited portions of Cobian nor Helland a lead assembly "wherein the first conductor and the second conductor are rotatable relative to one another," as recited in claim 1, nor a lead assembly "comprising . . . a first conductor and a second conductor . . . the second conductor disposed within and rotatable relative to the first conductor," as recited in claim 11. Rather, Helland (wherein the Office Action submits the missing subject matter may be found) recites "the active fixation helix . . . is secured to a conductive plug 176 . . . [the latter of which] may be movable or fixed with respect to the lead body 122 and rigid insulating element 180." (Col. 5, lines 9-13). Applicant submits that the moving of conductive plug 176 does not necessary require that "the first conductor and the second conductor are rotatable relative to one another" or that "the second conductor is rotatable relative to the first conductor" as claimed by Applicant.

Because neither Cobian nor Helland teaches or suggests all of the claimed subject matter of Applicant's claims 1 and 11, Applicant respectfully requests withdrawal of the rejection of such claims. Claims 2-7 and 9-10 are dependent on claim 1, and claims 12-13, 15-17, and 30-31 are dependent on claim 11, all of which are patentable over Cobain and Helland for the reasons stated above, in addition to the elements and/or limitations in such claims.

Claim 21:

The subject matter of claim 21 has been incorporated into respective independent claim 18; claim 21 has been canceled. Applicant submits that the Office Action has failed to make out a *prima facie* case of obviousness for (now canceled) claim 21, and thus claim 18, because not all claim elements and/or can be found in Cobian nor Altman (either individually or in combination), as required by M.P.E.P. § 2142, and because there is legally insufficient motivation to combine such references, as required in *In re Lee*.

In addition to the foregoing grounds set forth supporting the patentability of Applicant's claims 18, 20, and 23, Applicant cannot find in the cited portions of Cobian nor Altman "[a]

method comprising . . . disposing one or both of polyurethane or polyimide tubing between the first conductor and the second conductor,” as recited in Applicant’s claim 18. Rather, Altman (wherein the Office Action submits the missing subject matter may be found) recites “[a] method for manufacturing [a] . . . coiled cable lead . . . [wherein] each cable is coated with a fluoropolymer, polyimide or polyurethane coating and placed in a winder apparatus.” (Col. 2, lines 34-36). What is claimed by Applicant in claim 11 is an insulative sleeve disposed between the first conductor and the second conductor, which is in addition to insulation on the coiled conductor(s).

Furthermore, Applicant cannot find any motivation to combine the teachings of Cobian with the teaching of Altman to make the specific combination that was made by Applicant in claim 21, as required by *In re Lee*. The Office Action must provide a specific reason to support an obvious rejection, e.g., a reason which is clear and particular and not a broad conclusory statement; however, no such reason has been provided. The assertion in the Office Action states that substituting one known lead insulating material for another would have been “an obvious design choice” in order to “effectively insulate the conductors so electrical signals associated with the heart can be accurately sensed and delivered.” (Office Action, page 4). Applicant submits that such assertion *prima facially* fails to satisfy the requirements of 35 U.S.C. § 103, as it fails to suggest a motivation to make a material substitution. Rather, as recognized by the Office Action, such assertion amounts to a “mere substitution of known functional equivalents.” (Office Action, page 4). Accordingly to the Federal Circuit, “[t]rade-offs often concern what is feasible, not what is, on balance, desirable. Motivation to combine requires the latter.” *Winner Int’l Royalty Corp.* at page 1587.

Because neither Cobian nor Altman teaches or suggests all of the claimed subject matter of Applicant’s claim 18, and no legally sufficient motivation to combine the subject matter of such references has been provided, Applicant respectfully requests withdrawal of the rejection of claim 18. Claims 20 and 23 are dependent on claim 18 and are patentable over Cobain and Altman for the reasons stated above, in addition to the elements and/or limitations in such claims.

Claims 23 and 27-28:

The subject matter of claim 27 has been incorporated into respective independent claim 24; claim 27 has been canceled. Applicant submits that the Office Action has failed to make out a *prima facie* case of obviousness for claims 23, 28, and (now canceled) claim 27, and thus claim 24, because not all claim elements and/or can be found in Cobian nor Helland (either individually or in combination), as required by M.P.E.P. § 2142, and because there is legally insufficient motivation to combine Cobian and Nelson, as required in *In re Lee*.

In addition to the foregoing grounds set forth supporting the patentability of Applicant's claims 18, 20, and 23 and claims 24-26 and 28-29, Applicant submits that using Cobian and Nelson alone (e.g., without the use of the Applicant's disclosure), one of ordinary skill in the art would not have been motivated to combine the teachings of such references to produce a method "comprising heat shrinking PTFE or ETFE on the second outer coil diameter," as recited in claims 23 and 24.

As one example, Cobian and Nelson teach against being combined with one another. Cobian recites "[i]n each of the above-described embodiments, it is assumed that all of the coiled wire conductors are insulated by a coiled insulative sheath that loosely receives it." (Col. 11, lines 62-64). Cobian additionally recites "[a]dvantageously, the coiled wire insulative sheaths loosely receiving the coiled wire conductors decrease[s] the probability that defects in the coiled wire insulative sheath will result in mechanical fracture or deterioration of the lead conductor or unacceptable changes in electrical resistance." (Col. 6, lines 1-5). In brief, Cobian relies on a gap between the coiled insulative sheaths and the associated conductors to enhance the overall survivability of a lead. On the other hand, Nelson recites "PTFE tubing 38 is heat shrunk onto the inner coil 34." (Nelson, col. 7, lines 46-48). As can be seen from FIG. 10 of Nelson and the text associated therewith, the heat shrinking of Nelson teaches away from leaving a gap, such as that relied on in Cobian, between tubing 38 and inner coil 34. (*Id.*, FIG. 10).

As another example, the Office Action appears to pick and choose among individual elements of assorted references to recreate the claimed invention without some teaching or motivation in the references to support their use in the particular claimed combination, as prohibited by *Symbol Technologies, Inc.*

Because no legally sufficient motivation to combine the subject matter of Cobian with the subject matter of Nelson has been provided, Applicant respectfully requests withdrawal of the rejections of claims 23 and 24. Claim 25-26 and 28-29 are dependent on claim 24 and are patentable over Cobian and Nelson for the reasons stated above, in addition to the elements in such claims.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 359-3276 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

JEFFREY P. BODNER

By his Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.

P.O. Box 2938

Minneapolis, MN 55402

(612) 359-3276

Date July 10, 2006

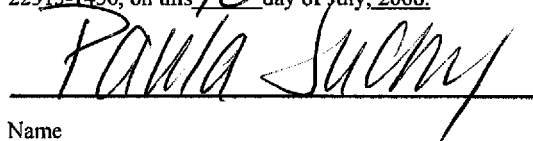
By


Catherine I. Klima-Silberg

Reg. No. 40,052

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